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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/508,977 | 03/17/2000 | THOMAS KIY | 1997/F-237 | 4908 |

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[REDACTED] EXAMINER

MARX, IRENE

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1651

DATE MAILED: 01/27/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/508,977

Applicant(s)

Kiy

Examiner

Irene Marx

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Nov 13, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 15-27 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 15-27 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

4) Interview Summary (PTO-413) Paper No(s). _____

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/13/02 has been entered. Claims 15-27 are being examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is vague, indefinite and inconsistent in the recitation "said biogenous substance being the biomass itself or a substance extracted from the biomass", inasmuch as the process is directed to producing "a biomass" and biomass is, in fact, harvested. There is no harvesting step for a biogenous substance or for the extraction thereof.

Claim 15 is further confusing in the recitation of "harvesting ... at an extraction rate of about 0.1 to about 12 times said volume per day". Does applicant mean a range of replacing 0.1 of the initial volume per day to replacing the total initial volume 12 times during one day? It is unclear that replacing 0.1 of the initial volume per day would constitute "continuous culture". Clarification is required.

Claim 26 is vague and indefinite in the multiple "and/or" clauses recited. It is uncertain that sedimentation and flotation and centrifugation, for example, would be used in the harvesting process.

Claim 26 is confusing in the recitation "the cells contained in the harvested biomass", since biomass constitutes cells. It is recommended that this phrase be replaced by "wherein the produced biomass is separated from the harvested culture medium", if appropriate.

Claim 27 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. It is well recognized by those of skill in this art that ciliate biomass comprises substances such as proteins, peptides, enzymes, etc. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. .

With respect to claim 16, the recitation "one of the taxonomic groups..." followed by "including the orders..." and "which include..." renders the claim indefinite because it is unclear whether the limitation(s) following the phrase "including the orders..." and "which include..." are part of the claimed invention or not, and the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. In addition, the nature of the wild-type strains, mutants and recombinants intended is unclear in the context of broad taxonomic groupings as recited herein.

The claims 15-27 would be allowable upon resolution of all 35 U.S.C § 112 issues. The claims are free of the art of record, because the process steps used in the prior art for the cultivation of ciliates differ from those claimed herein in that in the instant case the biomass is harvested continuously from the complex axenic medium. There would have been no motivation for one of ordinary skill in the art to modify the processes of the prior art relating to the cultivation of ciliates in the manner claimed at the time the claimed invention was made.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

Irene Marx
IRENE MARX
PRIMARY EXAMINER